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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,890	08/28/2000	Oliver Brustle	V0S-012	7106
23483	7590	11/20/2007	EXAMINER	
WILMERHALE/BOSTON			FALK, ANNE MARIE	
60 STATE STREET			ART UNIT	
BOSTON, MA 02109			PAPER NUMBER	
			1632	
			NOTIFICATION DATE	
			DELIVERY MODE	
			11/20/2007	
			ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 09/581,890	Applicant(s) BRUSTLE, OLIVER	
	Examiner Anne-Marie Falk, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 106-114, 118-124, 137 and 138 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 106-114, 118-124, 137 and 138 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>0807 & 0803</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed August 22, 2007 (hereinafter referred to as "the response") has been entered. Claims 106, 118, 137, and 138 have been amended and Claims 116, 117, 126-133, 135, 136, and 139 have been canceled.

Accordingly, Claims 106-114, 118-124, 137, and 138 remain pending in the instant application.

The rejection of Claims 106-114, 116-124, 126-133, and 135-139 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement due to the presence of new matter, is withdrawn in view of the amendments to the claims to remove recitation of the "regional identity unrestricted, pluripotent" terminology and further in view of the cancellation of Claims 116, 117, 126-133, 135, 136, and 139.

The rejection of Claims 137-139 under 35 U.S.C. 112, first paragraph, for lack of enablement over the full scope, is withdrawn in view of the amendments to the claims to remove glial cells from the claimed composition and further in view of the cancellation of Claim 139.

The rejection of Claims 106-114, 116-124, 126-133, and 135-139 under 35 U.S.C. 112, second paragraph, for indefiniteness, is withdrawn in view of the amendments to the claims to remove recitation of the "regional identity unrestricted, pluripotent" terminology and further in view of the cancellation of Claims 116, 117, 126-133, 135, 136, and 139.

Information Disclosure Statement

At page 8 of the response, Applicants contend that the 1449 dated August 22, 2003 was not initialed and returned with any of the Office Actions that have issued in this Application. Applicants are advised that the information disclosure statement received on August 25, 2003 was considered on

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September 15, 2003 and a copy of the initialed and signed 1449 was provided to Applicants with the Advisory Action of October 3, 2003. See box 9 of the Advisory Action. A duplicate copy of the initialed and signed 1449 is provided herewith. The 1449 newly submitted on August 22, 2007 has been signed, but the references have not been initialed because they are duplicates of references already considered. A copy of the newly submitted 1449 is provided herewith.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 106-114, 118-124, 137, and 138 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,980,885 (Weiss et al., 1999; filed June 7, 1995), for reasons of record as applied to the previously pending claims in the Office Action of 8/14/06.

The claims have been amended so that they no longer include the new matter objected to in the prior Office Action. Accordingly, this art rejection is reinstated. The claims are directed to cell.

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compositions claimed in a product-by-process format. The claims cover heterogeneous cell compositions comprising neural precursor cells and other types of differentiated neural cells.

The instant claims are product-by-process claims. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production. See M.P.E.P. 2113. Thus, the claims read on neural stem cells disclosed in the prior art, for the reasons set forth herein below and reasons of record.

The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis original). For the purpose of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See MPEP 2111.03.

Weiss et al. (1999) disclose mammalian neural stem cells. These cells can be derived from embryonic, juvenile, or adult mammalian neural tissue. The cells can be induced to differentiate into neurons, astrocytes, and oligodendrocytes. Although the instantly claimed cells are limited to cells derived from embryonic stem cells, no particular identifying characteristics are recited in the claims other than the requirement that the cells differentiate into “neuronal cells or glial cells” or just “glial cells.” The cells disclosed by Weiss et al. satisfy this limitation. Weiss et al. further disclose that the neural stem cells form neurospheres in suspension culture (Columns 33-34). The specification particularly states that “[i]n the continued presence of a proliferation-inducing growth factor such as EGF or the like, precursor cells within the neurosphere continue to divide resulting in an increase in the size of the neurosphere and the number of undifferentiated cells.” Example 6, *inter alia*, provides a disclosed embodiment of a cell composition comprising 100% neural cells and neural precursor cells, as instantly claimed. The example discloses that neurospheres were dissociated and single cells from the dissociated neurospheres were

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suspended in tissue culture flasks. A percentage of dissociated cells began to proliferate and formed new neurospheres largely composed of undifferentiated cells. Thus, both the starting material (i.e., the single cell suspension) and the final culture of Example 6 represent cell compositions as claimed. The reference further discloses that the neural stem cells are non-tumorigenic (Column 1, lines 39-44) and can be used for autologous transplantation (Column 1, lines 49-50).

In the absence of evidence to the contrary, the neural stem cell compositions disclosed by Weiss et al. are indistinct from the cell compositions instantly claimed.

Thus, the claimed compositions are disclosed in the prior art.

Conclusion

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your

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questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

/Anne-Marie Falk/
Primary Examiner, Art Unit 1632